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Clinical Trial Billing Compliance

Presented by Allecia Harley

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Learning Objectives

- Upon completion of this presentation you will be able to:
- Define a “Qualifying Clinical Trial”
- Identify items and services that are and are not covered by the Clinical Trial Policy (CTP)
- Outline the steps of a coverage analysis

Historical Perspective on Clinical Research Billing Compliance

Overview and Historical Perspective

- Medicare coverage of **investigational devices** has been in place since 1995 with minor changes in multiple years
- Medicare's **Clinical Trial Policy** (CTP) has been in place since 2000 with minor changes and actual naming in 2007
- The Rush University Medical Center **settlement of** 2005 initiated the attention and focus on interpreting and complying with the CTP for many academic medical centers

Overview and Historical Perspective

- CMS created an **integrated data repository** to be used in identifying improper payments[1]
  - Double-billing can be considered fraud

- **Health care reform legislation** requires the following:
  - Commercial payers to cover routine care for some research[2]
  - Increased funding for Medicaid fraud and abuse control

[1] CMS Integrated Data Repository (IDR) Overview, www.cms.gov/IDR/ .

[2] Section 10103 of the Patient Protection and Affordable Care Act (PPACA).

Overview and Historical Perspective

Why is this important?

- Public Settlements
  - University of Alabama settlement for $3.4 million, 2005
  - Weill Cornell Medical Center settlement for $4.3 million, 2005
  - Rush University Medical Center settlement for $1 million, 2005
  - Tenet Healthcare System, Norris Cancer Center for $1.9 million, 2010
- Integrity of the research
- Trust of sponsors and research participants
- Attention to accurate budgeting to ensure appropriate use of research dollars
- Assurance that all research dollars are captured (under-billing is as or more common than over billing)

Medicare’s Clinical Trial Policy (CTP)

CMS Clinical Trial Policy

- "Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply."
- Defined "routine costs" by inclusion and exclusion
- Outlined a qualifying analysis (4 steps)

CMS Clinical Trial Policy
Qualifying Clinical Trials (QCT)

- A clinical trial must "qualify" in order for routine costs to be covered by Medicare
- A qualifying clinical trial meets all 4 of the following requirements:
  1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids)
  2. The trial must have therapeutic intent. It cannot be designed exclusively to test toxicity or disease pathophysiology
  3. The trial must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group
  4. The trial must be "deemed" to meet CMS' 7 desirable characteristics of a clinical trial

Clinical Trial Policy- Qualifying Clinical Trial
Requirement #1-Medicare Benefit Category

Trial must be an evaluation of an item or service that falls within a Medicare benefit category such as:

- Drugs and Biologics
- Laboratory and Diagnostic Services
- Medical and Surgical Procedures
- Diagnostic Imaging
- Medical Devices and Prosthetics
- Durable Medical Equipment

The above mentioned Medicare benefit categories are not exhaustive

Clinical Trial Policy- Qualifying Clinical Trial
Requirement #2 – Therapeutic Intent

The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent:

- Overall Survival
- Tumor Response
- Efficacy

Phase I Quandary:

- Safety and Toxicity
- Maximum Tolerated Dose
- Pharmacokinetics
- Usually healthy volunteers

However, Phase I research of some conditions like cancer and HIV enroll participants with diagnosed disease.

Clinical Trial Policy- Qualifying Clinical Trial

Requirement #3 – Diagnosed Disease

Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

- Pregnancy is considered an “illness”
- Therapeutic interventions may also have healthy controls

Clinical Trial Policy- Qualifying Clinical Trial
Requirement #4 – Deemed Status

Trials must be deemed to meet the seven desirable characteristics

- Desirable Characteristics:
  - The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
  - The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
  - The trial does not unjustifiably duplicate existing studies;
  - The trial design is appropriate to answer the research question being asked in the trial;
  - The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
  - The trial is in compliance with Federal regulations relating to the protection of human subjects; and
  - All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Clinical Trial Policy- Qualifying Clinical Trial
Requirement #4 (continued)

Trials must be deemed to meet the seven desirable characteristics

- No system for self-certification as originally intended
- No review mechanism at CMS as with IDE device trials

Deemed trials are:

- Trials funded by NIH, CDC, AHRQ, HCFA (CMS), DOD, and VA;
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, HCFA, DOD and VA;
- Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1)

Polling Question 1

There is a Phase 1 drug study enrolling patients diagnosed with lung cancer. The study is being conducted under an IND and the objective of the study is to evaluate safety and toxicity. Is this a qualifying clinical trial under the CTP?

A. Yes
B. No
C. Not sure

CMS Clinical Trial Policy
Routine Cost Determinations

- Routine costs in qualifying clinical trials are covered under the CTP
- Routine costs include items and services:
  - Typically provided absent a clinical trial (e.g., conventional care);
  - Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent);
  - Items or services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
  - Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications

CMS Clinical Trial Policy
Routine Cost Determinations

- Routine costs in clinical trials exclude:
  - The investigational item or service itself unless otherwise covered outside of the clinical trial;
  - Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
  - Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial

Polling Question 2

What is not considered a “routine cost” under the CTP?

A. A physical exam that is considered conventional care
B. A CT scan being performed solely to measure the primary endpoint
C. A lab test being performed to monitor the effects of the investigational drug
D. Costs associated with the administration of the investigational chemotherapy drug

Coverage for Medical Devices
How is it Different than for Drugs?

- There are two categories for devices:
  - Category A Devices: Experimental - innovative devices for which absolute risk of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type is safe and effective).
  - Category B Devices: Non-experimental and/or investigational devices where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.
- The FDA IDE approval letter will contain the device category determination

CMS IDE Device Regulations
Category B (coverage since 1995)

Category B devices are covered if approved by the Contractor Medical Director

What about the items and services provided over the course of the trial related to the device?

Regulations say:

- "Routine care services related to a [Category B] device that is furnished in conjunction with an FDA approved clinical trial" (See 405.407 (b)(3))

CMS IDE Device Regulations
Category A (trial coverage since 2003)

Category A devices are NOT covered. They are experimental/investigational by definition and thus, do not meet the threshold requirement

However, the trial services can be covered in a Category A study

Regulations say:

- "Routine care services related to a [Category A] device furnished in conjunction with an FDA approved clinical trial" (See 405.407 (b)(2))

Coverage Analysis

Coverage Analysis (CA) Defined
What is it?

- A CA is a systematic review of research-related documents to determine the Medicare qualifying status of the study itself and the Medicare billing status of the items and services provided to the research subjects over the course of the research.
- The CA should be conducted prior to or in tandem with the budgeting process to ensure coverage for all items and services in the clinical trial and provide a fact-based platform for contract negotiation.
- The CA is the mechanism for compliance with the billing rules.

Coverage Analysis (CA) Defined

- Why is the focus on the Centers for Medicare and Medicaid Services (CMS) rules?
  - CMS tends to set the standard for reimbursement
- Drug and device trials are subject to different billing rules and regulations

Trial Type	Regulation
Non-Device	-CMS' Clinical Trial Policy (CTP) -National and Local Coverage Determinations*
Device	-Medicare Modernization Act of 2003 -42 CFR 405.201-405.215, 411.15, and 411.406 -Medicare Benefit Policy Manual Chapter 14 -National and Local Coverage Determinations*

** Medicare issues National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) to disseminate reimbursement decisions for specific items and services*

Benefits of Conducting a CA

- Early detection of items and services not covered by Medicare or the involved payer
  - Develop a spreadsheet of all the patient care costs in the study
  - Determine if the trial qualifies for reimbursement under Medicare's/the payer's criteria
  - Identify costs not covered by insurance or the study sponsor

- Development of a tool to ensure compliant claims processing
  - Identify the claims to be split before billing
  - Identify the services that need research specific codes and/or modifiers
  - Identify the charges to be submitted to the study sponsor

Benefits of Conducting a CA

- Medicare's expanded coverage of clinical trials* means increased opportunities for reimbursement of the following:
  - Services typically provided to patients with the disease under study (e.g., conventional care)
  - Services provided to administer a drug, implant a medical device, or deliver a service
  - Clinically appropriate monitoring of the drug, medical device or service
  - Prevention, diagnosis and/or treatment of complications

* CMS National Coverage Decision on the Routine Costs of Clinical Trials (310.1) , 2000 and 2007.

CA Description

CA is really multiple analyses:

- Qualifying Clinical Trials Analysis (QCT)
- Items and Services Analysis
  - FDA status of investigational item
  - What is paid for/provided by Sponsor (Contract and ICF review)
  - Review of Medicare Billing Rules for each item/service

CA Description

Documentation of CA is essential for compliance

- Provides evidence of due diligence
- Detailed citations support billing determinations
  - Recommendation - use narrative (Memo) and spreadsheet (Grid) documents
- If it's not documented, it didn't happen
- Goal is to have an CA that is replicable without your having to explain

Coverage Analysis for Device Studies

- No qualifying test *per se;* a QCT analysis is not done for device studies
- There are additional compliance steps for coverage purposes:
  - Contractor approval is needed pre-study billing
  - Best practice – conduct the CA, submit the items/services analysis with the approval request and document results
- "Medicare contractors may approve coverage for any device with an FDA approve IDE categorization as a non-experimental/investigational if all other coverage requirements are met." [See 405.211(b)]
- "Medicare contractors must consider whether any restrictions concerning site of service, indications for use, or any other list of conditions have been placed on the device's use." [See 405.211(c)]

Polling Question 3

Which is not a benefit of conducting a coverage analysis?

A. Compliance
B. Decreased possibility of double billing
C. Increased opportunities for reimbursement
D. Identification of potential issues with study procedures
E. None of the above – all are benefits

Steps for Conducting a Coverage Analysis

CA Documentation

- Sample QCT Analysis

Qualifying Clinical Trial Analysis

Does the Clinical Trial meet the necessary Requirements?

Requirement	Yes	No	Comment
Does the investigational item or service fall into a Medicare benefit category?	X		The investigational product is a member of Medicare benefit category of Medical and Surgical Procedures.
Does the study have therapeutic intent in the primary objective?	X		Yes, the specific aims of the study are to determine the effect of induced cooling after severe Traumatic Brain Injury (TBI) in children (Study Protocol, pgs 7-8)
Does the study enroll patients with diagnosed diseases?	X		This protocol enrolls participants with a diagnosis of Traumatic Brain Injury (Study Protocol, p. 15)
Is the study a deemed trial?	X		This study is supported by funding from the National Institute of Neurological Disorders and Stroke
Is the study a qualifying clinical trial?	X		

Sponsor Agreement (Contract) Review

The Contract Services Agreement (Appendix A) specifies payment for the following participant care costs:

- 1 Run-in Patient and consenting, randomization and successful management of 2 additional subjects
- The 3, 6, and 12 month outcomes

Informed Consent Review

In the Informed Consent Form Version Date 9/17/07, the financial disclosure language promises that the participant and their insurer will not be billed for any equipment used specifically for this study, nor any functional tests specifically related to the study.

CA Documentation

- Sample Billing Grid

Study 123						
A Phase I and Phase II Trial of Neoadjuvant Treatment with Wonder Drug A plus Wonder Drug B in Postmenopausal Patients with Hormone Receptor Positive Breast Cancer						
This Medicare coverage analysis is intended as a general guideline for use in determining which items and services are billable to Medicare based upon current benefit policies, coverage determinations, coverage decisions, and federal guidelines. All items and services that are billable to Medicare must be supported by medical necessity.						
Items and Services	Screening / Baseline	On Study Evaluation Every 28 Days	End of Wonder Drug B Presurgical Visit	Post-Surgical Visit Treatment Unblinding	End of Therapy Withdrawal[b]	Comments
Informed Consent	X					This item is captured as part of Time and Effort (T&E)
Medical History	X	X	X	X	X	This item is not separately billable when a billable Evaluation and Management Service is performed.
Physical examination	SOC	SOC	SOC	SOC	SOC	Evaluation and Management (E&M) services are billable to Medicare per Medicare Claims Processing Manual Chapter 12, Section 30.6.
Performance Status	X	X	X		X	This item is not billable.
Toxicity Assessment	X	X	X		X	This item appears to be for research purposes only. Research laboratory tests are billable to the Sponsor per ICF, p. 7.
Clinical tumor status	SOC	SOC	SOC		SOC	This item is considered routine care per National Comprehensive Cancer Network Guidelines. It is billable to Medicare per CMS NCD 310.1 (the protocol lists either physical examination or imaging procedures to conduct the tumor assessment).
Electrocardiogram (ECG)	X					This item appears to be for research purposes only. It is billable to the Sponsor per ICF, p. 7.
Echocardiogram or MUGA	SOC	SOC	SOC		SOC	These items are considered routine care per National Comprehensive Cancer Network (NCCN) Guidelines. Echocardiogram is billable to Medicare per CMS NCD 20.15, MUGA per Medicare Benefits Policy Manual Chapter 15, Section 80.
Dynamic MRI[a]	X	X*	X			This item is billable to the Sponsor per ICF, p. 7.
CBC, differential, platelet count	SOC	SOC	SOC	SOC	SOC	These items are considered routine care per National Comprehensive Cancer Network Guidelines. Labs are billable to Medicare per Medicare Benefits Policy Manual Chapter 15, Section 80.1.
Serum Chemistries (electrolytes, creatinine, total bilirubin, alkaline phosphatase, AST, ALT)	SOC	SOC	SOC	SOC	SOC	
HER2 status (by FISH; local lab)	SOC	SOC	SOC	SOC	SOC	
Hormone Receptor status (IHC; local lab)	SOC					
Radiologic Assessment to exclude distant metastases[c]	SOC					Radiologic assessments (CT, MRI, ultrasound, etc.) are considered routine care per NCCN guidelines. They are billable to Medicare per CMS NCD 310.1 (the protocol does not specify the service/procedure).
Research blood specimens[d]	X					These items are billable to the Sponsor per ICF, pgs. 3 and 7.
Core biopsy/tumor tissue collection (snap frozen and paraffin-embedded)	X		X[f]			
Survival; interval therapies/procedures					X	This item is not billable.
Anastrozole (Daily, PO)	SOC	SOC	SOC			This item is considered routine care per NCCN guidelines. It is billable to Medicare per Medicare Benefits Policy Manual Chapter 15, Section 50.5.3 (oral anti-cancer drugs).

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CA Description and Step-by-Step Instruction

Step One - Gather Relevant Documents

- Research Protocol
- Protocol-Specific Informed Consent Form (ICF) and IRB approval status
- Clinical Trial Agreement (CTA) or Notice of Grant Award
- Budget
- Documentation of the drug or device status with the FDA (e.g. IND, IDE, 510k approval), if available
- Carrier and/or Fiscal Intermediary Letter documenting approval for billing of the drug, devices, and/or protocol related services, if MCA conducted after approval

CA Description and Step-by-Step Instruction

Step One – Gather Relevant Documents

When conducting a CA, the sections of the protocol that are most relevant are:

- Title Page (IND, Version Date, Sponsor)
- Study objectives (i.e. primary and secondary objectives)
- Study procedures (i.e. study design, methodology, research plan, etc.)
- Schedule of events (i.e. activity flow chart, calendar, etc.)
- Patient population (i.e. inclusion criteria, patient selection, etc.)

CA Description and Step-by-Step Instruction

Step One – Gather Relevant Documents

Research Protocol Cont.:

- The study procedures and schedule of events can be used to add the items and services to the billing grid. Do not assume that all items and services are listed in the schedule of events.
  - Always cross reference the two sections and make sure the investigational product as well as other drugs or devices appear in your documentation of the analysis.
- The patient population section will inform you of the kinds of patients that will participate in the study. You will need to know if this study is for healthy volunteers or people that have been diagnosed with a disease.

CA Description and Step-by-Step Instruction

Step One – Gather Relevant Documents

The Informed Consent Form

- The costs section of this document should describe what the patient and/or their insurer will be charged.
  - If an item is promised at no cost to the patient, it cannot be billed to the patient or their insurer.
- The benefits section of this document should provide insight into the therapeutic intent of the trial. If this section says there is no potential benefit to participants in the trial, it is possible that evidence of therapeutic intent cannot be found. However, the ICF is often more conservative on this point than other study documents and this should be taken into account.

CA Description and Step-by-Step Instruction

Step One – Gather Relevant Documents

Documentation of Investigational Drug or Device Status with the FDA

- Unapproved pharmaceuticals, biologics, and medical devices must be approved for testing by the FDA before a clinical trial is initiated. The IND numbers assigned are confidential and not publicly posted.
  - Drugs get an investigational new drug (IND) number
  - Biologics (vaccines, blood products, gene therapies) get a BB-IND number
  - Devices get an investigational device exemption (IDE) number
- A sponsor can request approval for a single protocol in a specific phase or a combination of protocols and/or phases.
- Ideally, you will receive a copy of a letter from the FDA with the appropriate approval number that includes the protocol title you are reviewing. However, these are sometimes held back as proprietary. In which case, the IND number from the protocol or an email confirming the IND # should be sufficient.

CA Description and Step-by-Step Instruction

Step Two – QCT Analysis

Is the study an investigation of a product/service that is covered by Medicare?

- Very Broad Categories:
  - Drugs, Biologics and Therapeutics
  - Laboratory and Diagnostic Services
  - Medical and Surgical Procedures
  - Diagnostic Imaging
  - Medical Devices and Prosthetics
  - Durable Medical Equipment
- Review of the following items should provide answers to this question:
  - The protocol title
  - Study rationale
  - Study objectives

CA Description and Step-by-Step Instruction

Step Two – QCT Analysis

Does the study have therapeutic intent? (for the participants in the study)

- Review of the following items should provide answers to this question:
  - The Study Objectives/Goals/Aims
  - Study Rationale
  - Study Endpoints

- Note: TI in the primary objective is optimal. However, if there are multiple objectives, cite to the objective.

CA Description and Step-by-Step Instruction

Step Two – QCT Analysis

Does the study enroll participants with a diagnosed disease?

- Review of the following items should provide answers to this question:
  - The Study Inclusion/Exclusion Criteria
  - Informed Consent Form

CA Description and Step-by-Step Instruction

Step Two – QCT Analysis

Is the study "deemed"?

- Review of the following items should provide answers to this question:
  - The Protocol Title Page (Sponsor or IND information)
  - FDA Correspondence
  - Sponsor Correspondence
  - IND Exemption Analysis
  - CMS Coverage with Evidence Development Documentation

CA Description and Step-by-Step Instruction

Step Two – QCT Analysis

REMEMBER

A Study must meet all FOUR criteria to be considered qualified for the reimbursement of routine costs

CA Description and Step-by-Step Instruction

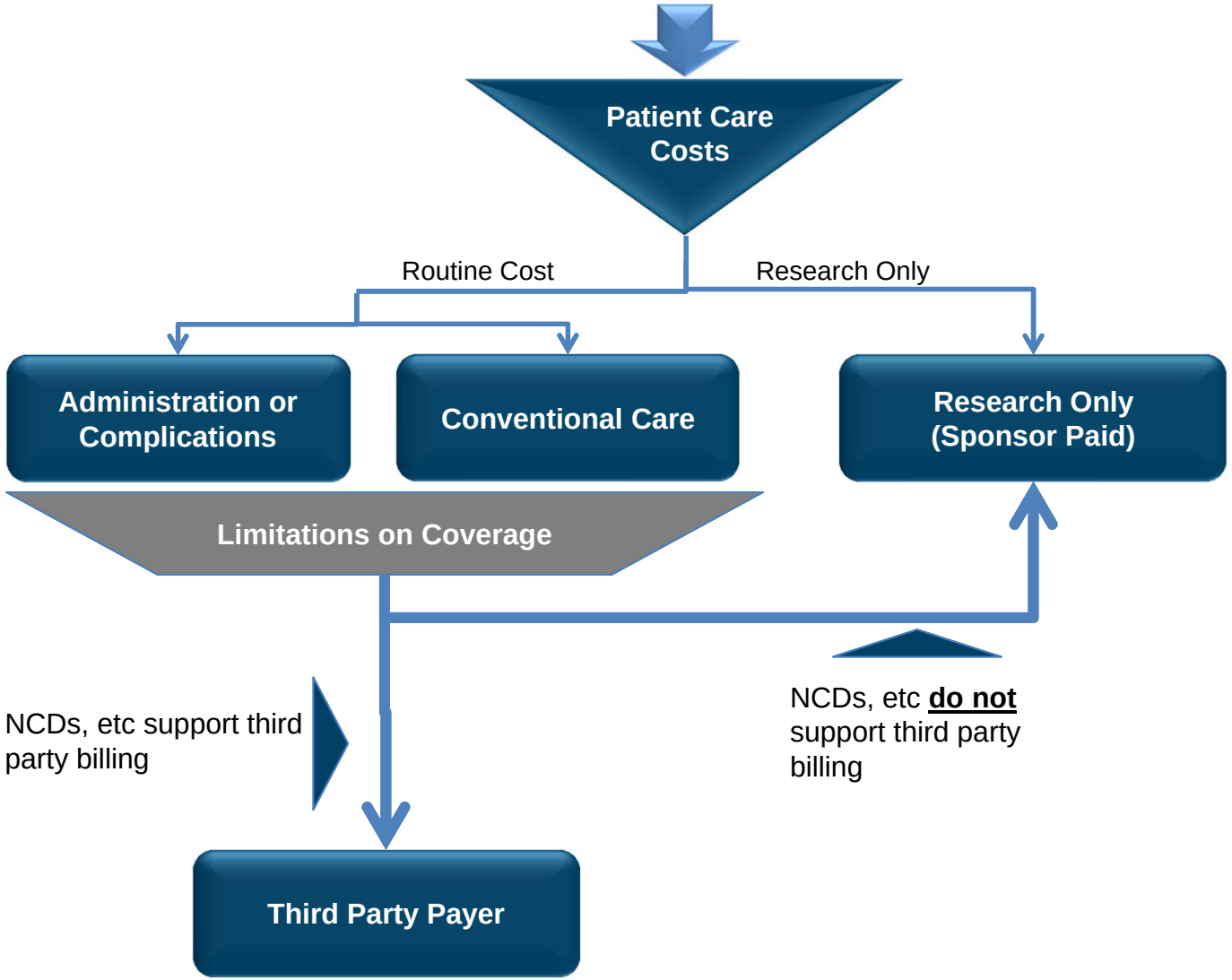
Step Three – Items and Services Analysis

What items and services will participants receive as part of the study?

- Build a billing grid
- Review of the following items should provide answers to this question:
  - The Protocol Schedule of Events
  - The Study Methodology or Procedures
  - Informed Consent Form
- Be Specific:
  - Items and services may be coded using CPT Codes during the budgeting and/or billing process.
  - Document Only Items that are Part Of/Essential to the Research:
    - Adverse Events DO NOT need to be listed
    - Sometimes protocols list more than research

CA Description and Step-by-Step Instruction

Step Three – Items and Services Analysis



CA Description and Step-by-Step Instruction

Step Three – Items and Services Analysis

What items are paid for or provided by the Sponsor (research-only)?

- Review of the following items should provide answers to this question:
  - The Study Protocol
  - The Contract or Clinical Trial Agreement
  - Informed Consent Form

CA Description and Step-by-Step Instruction

Step Three – Items and Services Analysis

Coding payer determinations in the billing grid:

- R- Billable to Sponsor or Research Account
  - These items may be listed as paid by the sponsor
  - These items are provided by the sponsor
  - These items are experimental or provided solely for the purpose of data collection
  - These items are promised to the subject free of charge
  - These items are related to time and effort or do not generate a charge (e.g. Study Questionnaire, Informed Consent)

CA Description and Step-by-Step Instruction

Step Three – Items and Services Analysis

Are the remaining items considered “routine costs”?

- Routine care determinations are either objective or subjective-will be an institutional decision
  - Can ask the PI what is considered to be standard of care for the illness or injury being studied and what s/he basis these decisions on
  - Answers could range from objective national criteria (National Comprehensive Cancer Network Guidelines) or objective local criteria (department critical care pathways/care maps/guidelines) or subjective criteria (typical practice patterns)

CA Description and Step-by-Step Instruction

Step Three – Items and Services Analysis

Coding payer determinations in the billing grid:

- P - Billable to Payer / Patient
  - These items may be provided to treat the patient outside of a clinical trial; and
    - These items are not listed as paid by the sponsor or any other entity (default)
  - These items may be solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent)
  - These items may be provided to monitor or prevent complications resulting from participation in the study
    - These items are not normally provided to treat the patient outside of a clinical trial, but are reasonable and necessary to protect the research subjects

CA Description and Step-by-Step Instruction

Step Three – Items and Services Analysis

For the items considered "routine costs," are there Medicare coverage decisions that preclude billing?

- National Coverage Decisions (NCD)
- Local Coverage Decisions (LCD)

Note: there may be a need for additional research of drugs and devices (FDA status, on or off-label use).

CA Description and Step-by-Step Instruction
Step Three – Items and Services Analysis

Provide detailed citations to justify payer determinations

- List the source of the routine care determination (based upon the institutions risk tolerance)
- List the source of the Medicare billable determination to justify the non-coverage (and provide a basis for negotiations with sponsors)
- Explain any exceptions or “qualifications”

CA Description and Step-by-Step Instruction

Step Four – Quality Assurance Review

Review your work

- Use the memo and grid as audit tools- follow the citations
- Spell check and review for complete sentences
- Ensure that all sections of the memo are complete
- Ensure that grid formatting is legible (print preview)

Questions for the Speaker?

Allecia A. Harley
Director, Huron Consulting Group

P 312.880.5628 | C 312.479.3293
aharley@huronconsultinggroup.com

Allecia Harley is a Director in the Research Solutions Practice at Huron Consulting Group, a leading provider of services to enable clients to more effectively manage the business of research and mitigate compliance risks. Prior to joining Huron, she worked in public, private, and non-profit organizations involved in bench and/or clinical research. Ms. Harley lives in Chicago and travels throughout the country to assist clients in efficient process design and effective process improvements.

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